K033613

DEC - 8 2003

ERA 300 Pacing System Analyzer
Special 510(k) Notification

1. 510(K) SUMMARY

Name and Address of Sponsor: BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	ERA 300 Dual Chamber Pacing System Analyzer
Classification:	Class II/III
Classification Name:	External Pacemaker Pulse Generator (21 CFR 870.3600) Pacemaker Electrode Function Tester (21 CFR 870.3630) Pacemaker Generator Function Analyzer (21 CFR 870.3720)
Product Code:	DTA, DTC, DTE

Date Prepared: November 14, 2003

General Description:
The ERA 300 is a portable, dual chamber pacing system analyzer designed to test the electrical performance of the pulse generator and the pacing lead system or operate as a temporary external pulse generator at the time of pacemaker implantation and during invasive pacemaker troubleshooting or evaluation procedures. The ERA 300 utilizes a touch-proof configuration to help prevent hazardous connection between patients and electrical power sources.

Device Modification:
A plastic foil was applied to four sides of the battery in order to reduce movement of the battery within the compartment, thereby reducing the number of sudden power-offs of the ERA 300.

Predicate Devices:
BIOTRONIK proposes the following Pacing System Analyzer cleared through 510(k) notification as a predicate device for the ERA 300 Pacing System Analyzer:

- BIOTRONIK's ERA 300 Pacing System Analyzer (#K964190, cleared 07-10-97)

Indications for Use:
The ERA 300 is intended for use during invasive pacemaker procedures in the following activities:

- **Temporary External Pacing**
  Provides temporary stimulation under DDD, DDI, DOO, VVI, VDD, VOO, AAI, or AOO modalities during implantable pacemaker procedures or physician evaluations.
- **Lead Threshold Determination**
  Determines in situ lead characteristics of impedance, capture threshold, P/R wave amplitude and P/R wave slew rate. Determines the in vivo retrograde conduction time.
- **Pacemaker Function Test**
  Tests and analyzes the in vitro operation of external or implantable pulse generators. Determines the following parameters: pulse amplitude and width, sensitivity, refractory period, A/V delay, and rate/interval.

Name and Address of Manufacturing Site: BIOTRONIK GmbH & Co. (reg. no. 9610139)
Woermannkehre 1, 12359 Berlin, Germany
Phone: 011-49-30-689-05-304

Name and Address of Contract Manufacturing Site: BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6, 8180 Bülach, Switzerland
Phone: 011-41-1-864-5169

Contact Person and Phone Number: Jon Brumbaugh
Director, Regulatory Affairs
Phone: (888) 345-0374
Fax: (503) 635-9936

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2003

BIOTRONIK, Inc.
c/o Mr. Jon Brumbaugh
Director of Regulatory Affairs
6024 Jean Road
Lake Oswego, OR 97035

Re: K033613
Trade Name: ERA 300 Dual Chamber Pacing System Analyzer
Regulation Number: 21 CFR 870.3600, 870.3630 and 870.3720
Regulation Name: External Pacemaker Pulse Generator
Pacemaker Electrode Function Analyzer
Pacemaker Generator Function Analyzer
Regulatory Class: Class III (three)
Product Code: DTA, DTC and DTE
Dated: November 14, 2003
Received: November 17, 2003

Dear Mr. Brumbaugh:

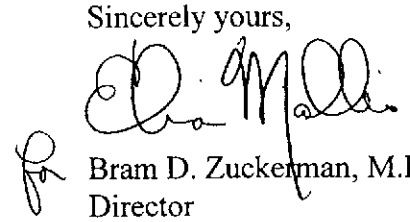
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

The ERA 300 is intended for use during invasive pacemaker procedures in the following activities:

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See **Appendix 1** for FDA's 510(k) Indications for Use Form.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033613